UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,211	02/17/2004	Rainer Kuth	P03,0622	9905

7590 02/11/2008

SCHIFF HARDIN LLP
Patent Department
6600 Sears Tower
233 South Wacker Drive
Chicago, IL 60606

EXAMINER	
SEREBOFF, NEAL	
ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
02/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,211	KUTH ET AL.	
	Examiner	Art Unit	
	NEAL R. SEREBOFF	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant/ Response to Amendment

1. Regarding the amendment dated 12/20/2007, the following has occurred: Claims 7 and 8 have been amended; Claims 9 – 11 have been added. Claims 1 – 11 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim includes the limitation "querying a patient" found on the first line of the claim. The Examiner looked at the Detailed Description and is using paragraph 22 to understand how to understand this limitation. Detailed Description, paragraph 22 states that the patient data can be queried so the Examiner understands querying a patient to be querying patient data.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. ***Claims 1 – 11*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Teshima, U.S. Patent Number 6,272,470 in view of Thangaraj et al., U.S. Pre-Grant Publication Number 2003/ 02008378.

7. As per claim 1, Teshima teaches a method to input and store data for a clinical study, comprising:

- Generating an input platform program for an input of data of a clinical study (column 8, lines 1 – 50 where the use of clinical study is considered non-functional);
- Distributing the input platform program to input locations (column 6, lines 45 – 58 where the locations are distributed through the Internet);
- Calling up and activating the input platform program dependent on a participant characteristic (column 13, lines 35 – 46 where the web page is called up), the participant characteristic being linked with a patient participating in the clinical study (column 12, lines 55 – 65);
- Inputting the data at an input location via an input platform generated by the input platform program (column 10, lines 23 – 31); and
- Storing the input data (column 11, lines 31 – 33).

Teshima does not explicitly teach the method comprising generating an input platform program for an input of data of a clinical study (when clinical study is used as functional language). However, Thangaraj teaches the method comprising generating an input platform program for an input of data of a clinical study (paragraphs 10 and 11 where the input parameters are customizable).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Teshima.

- One of ordinary skill in the art would have added this feature into Teshima with the motivation to create an Internet-based solution to clinical trial management (Thangaraj paragraph 5).
- The technical ability existed to add the Thangaraj feature into Teshima as claimed and the substitution result is predictable.

8. As per claim 2, Teshima in view of Thangaraj teaches the method of claim 1 as described above. Teshima further teaches the method wherein the input platform program is distributed in a framework of a medical data standard (column 1, lines 53 – 67 where the standard is DICOM).

9. As per claim 3, Teshima in view of Thangaraj teaches the method of claim 2 as described above. Teshima further teaches the method comprising storing the input platform program in a region of the medical data standard reserved for patient data (column 3, lines 8 – 15).

10. As per claim 4, Teshima in view of Thangaraj teaches the method of claim 1 as described above. Teshima further teaches the method wherein the storage of the data acquired at an input location ensues in a data format that is determined by the input platform itself (column 14, lines 26 – 34).

11. As per claim 5, Teshima in view of Thangaraj teaches the method of claim 4 as described above. Teshima further teaches the method wherein the acquired data are stored in a framework of a medical data standard (column 14, lines 26 – 34 where the standard is DICOM).

12. As per claim 6, Teshima in view of Thangaraj teaches the method of claim 4 as described above. Teshima further teaches the method wherein the acquired data are stored in a region of

the medical data standard reserved for patient data (column 11, lines 8 – 45 where the patient card contains patient data).

13. As per claim 7, Teshima in view of Thangaraj teaches the method of claim 2 as described above. Teshima further teaches the method wherein the Digital Imaging and Communication in Medicine (DICOM) standard is used as the medical data standard (column 14, lines 26 – 34).

14. As per claim 8, Teshima in view of Thangaraj teaches the method of claim 4 as described above. Teshima further teaches the method wherein the input platform program is distributed in a framework of a medical data standard that is the Digital Imaging and Communication in Medicine (DICOM) standard (column 14, lines 26 – 34).

15. As per claim 9, Teshima in view of Thangaraj teaches the method of claim 1 as described above.

Teshima does not explicitly teach the method wherein the clinical study input platform only permits input that are required for precisely this clinical study and that are incurred at the current input location in the examination of the study participant.

However, Thangaraj teaches the method wherein the clinical study input platform only permits input that are required for precisely this clinical study and that are incurred at the current input location in the examination of the study participant (paragraph 71 where the parameters are defined regarding patient use. Parameters set the boundaries of use and therefore only permit specific input).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Teshima.

- One of ordinary skill in the art would have added this feature into Teshima with the motivation to create an Internet-based solution to clinical trial management (Thangaraj paragraph 5).
- The technical ability existed to add the Thangaraj feature into Teshima as claimed and the substitution result is predictable.

16. As per claim 10, Teshima in view of Thangaraj teaches the method of claim 1 as described above.

Teshima does not explicitly teach the method wherein the generating of an input platform is performed by a research entity commissioning the study.

However, Thangaraj teaches the method wherein the generating of an input platform is performed by a research entity commissioning the study (paragraph 75 where the administrator sets up user functionality and paragraphs 82 and 83 that state that the clinical trial administrator is the same as the system administrator).

The Examiner takes Official Notice that a clinical trial administrator and the research entity commissioning the study can be the same. The Examiner therefore interprets the claim through this understanding.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Teshima.

- One of ordinary skill in the art would have added this feature into Teshima with the motivation to create an Internet-based solution to clinical trial management (Thangaraj paragraph 5).

- The technical ability existed to add the Thangaraj feature into Teshima as claimed and the substitution result is predictable.

17. As per claim 11, Teshima in view of Thangaraj teaches the method of claim 1 as described above.

Teshima does not explicitly teach the method comprising querying a patient as to whether the patient participates in the study, and, if so, in which form the patient participates in the study. However, Thangaraj teaches the method comprising querying a patient as to whether the patient participates in the study, and, if so, in which form the patient participates in the study (paragraph 129 where the data is queried. The Examiner notes that the 'form' is not defined and therefore understands that any query result is sufficient).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Teshima.

- One of ordinary skill in the art would have added this feature into Teshima with the motivation to create an Internet-based solution to clinical trial management (Thangaraj paragraph 5).
- The technical ability existed to add the Thangaraj feature into Teshima as claimed and the substitution result is predictable.

Response to Arguments

18. Applicant's arguments, see 35 U.S.C. 112 2nd paragraph rejections, filed 12/10/2007, with respect to claims 7 and 8 have been fully considered and are persuasive. The 35 U.S.C. 112, 2nd paragraph rejections of claims 7 and 8 have been withdrawn.

19. Applicant's arguments filed 12/20/2007 have been fully considered but they are not persuasive. The Applicant's arguments focus on the prepositional phrase, "of a clinical study." The phrase represented non-functional descriptive information about the data was therefore given no patentable weight (MPEP 2106.01).

20. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Conclusion

21. The Examiner has carefully reviewed the originally filed information for patentability. The Applicant is encouraged to re-consider any additional amendments in light of the cited art and the US Supreme Court decisions.

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEAL R. SEREBOFF whose telephone number is (571)270-1373. The examiner can normally be reached on Mon thru Thur from 7:30am to 5pm, with 1st Fri off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. S./
Examiner, Art Unit 3626
2/1/20008

/C. Luke Gilligan/
Primary Examiner, Art Unit 3626